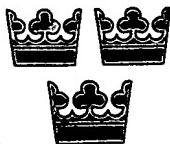


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For the Patent- and Registration Office

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## RECTAL INSERTION DEVICE

### Field of the Invention

- 5    The present invention relates to a rectal insertion device for the treatment of disorders of the digestive tract of a human or animal patient having a body comprising a forward section which in an operative position of the device is disposed in the anal canal of the patient and a first passageway which extends rearwardly in the device from a first forward opening in the forward section  
10   (hereinafter-in-part referred to as a "rectal insertion device of the type defined").

Disorders of the digestive tract which may be treated with rectal insertion devices of the type defined are colic, including infantile colic, haemorrhoids, constipation, gas and piles.

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### Background of the Invention

- A rectal insertion device of the type defined is made known in Applicant's International patent application publication WO99/30652. The first passageway is  
20   provided to channel faeces and gastrointestinal gases released on insertion of the forward section into the anal canal into a bag at the rear of the device. Some of the released faeces, however, may be ejected over the outer surface of the forward section instead of through the first passageway and thus not be collected in the bag.

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The aim of the present invention is to provide a rectal insertion device of the type defined with means for addressing this drawback with the prior art.

Summary of the Invention

According to the present invention there is provided a rectal insertion device of the type defined in which there is provided a rearward section having a forward end which in the operative position is disposed extra-corporeally and a second passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section. The second passageway acts to catch faeces discharged from the anal canal not caught in the first passageway. Preferably, in the operative position of the device the forward end of the rearward section abuts with the anus of the patient

In an embodiment of the invention such as the one hereinafter to be described the forward end of the rearward section has a transverse dimension greater than the transverse dimension of the forward section and the forward section extends forwardly from the forward end of the rearward section.

In an embodiment of the invention such as the one hereinafter to be described the forward section and rearward sections are co-axially arranged.

20 In an embodiment of the invention such as the one hereinafter to be described the second forward opening is an annulus formed around the forward section.

25 In an embodiment of the invention such as the one hereinafter to be described the first passageway communicates with the second passageway.

In an embodiment of the invention such as the one hereinafter to be described the second passageway has a rearward opening in the rearward section.

In an embodiment of the invention such as the one hereinafter to be described the rearward section of the device is a tube element having an open-ended axial lumen.

- 5 In an embodiment of the invention such as the one hereinafter to be described the device comprises an elongate shaft having a forward portion which presents the forward section of the device and a rearward portion which extends rearwardly from the forward portion into the lumen of the tube element and through which the first passageway extends

10

In an embodiment of the invention such as the one hereinafter to be described the first passageway has a rearward opening in the rearward portion of the elongate shaft.

15

In an embodiment of the invention such as the one hereinafter to be described the rearward portion of the elongate shaft is spaced from, and attached to, the wall of the lumen through one or more ribs.

20

An exemplary embodiment of the invention will now be described with reference to the accompanying Figures of drawings.

#### Brief Description of the Drawings

Figure 1 is a side view of a rectal insertion device in accordance with the invention.

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Figure 2 is a cross-sectional side view of the rectal insertion device of Figure 1.

Figure 3 is a perspective view of the rectal insertion device of Figure 1.

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Description of the Exemplary Embodiment

In the Figures of drawings there is shown a rectal insertion device 1 for treating disorders of the digestive tract of a human patient such as colic in accordance with 5 the invention which has been injection moulded from the polyether block amide Pebax™ (Elf Atochem).

The device 1 comprises a tube element 3 having an open-ended axial lumen 4 and an elongate shaft 5 which is co-axially mounted in the lumen 4 through rib 10 elements 6 so as to define an annulus 7 between the elongate shaft 5 and the lumen wall.

As can be seen, the elongate shaft 5 is divided into a rearward portion which is disposed inside the lumen 4 of the tube element 3 and a forward portion 8 which 15 protrudes from the lumen 4. The elongate shaft 5 has a channel 9 which extends axially therethrough from a forward opening 11 in a forward end 12 of the shaft 5 to a rearward opening 13 in a rearward end of the shaft 5.

The forward portion 8 of the shaft 5 is adapted for insertion into the anal canal of 20 the patient, as will hereinafter be described. To this end, the forward portion of the shaft 5 is provided with a coating which exhibits a reduced friction when wetted, e.g. the hydrophilic coating disclosed in Applicants European patent Nos. 0093093 and 0217771, and the forward end 12 of the shaft 5 is enlarged.

25 Arranged on a mid-section of the outer surface of the tube element 3 is a series of circumferential ribs 15 to assist an operator in gripping the device 1.

In use of the device 1, the operator inserts the enlarged forward end 12 of the elongate shaft 5 into the anal canal of the patient until the tube element 3 abuts the 30 anus. This is the operative position of the device 1. The abutment of the tube

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element 3 with the anus allows the length of the forward portion 8 of the elongate shaft 5 to be correct for the patient being treated, that is, so that the enlarged forward end 12 of the shaft 5 is positioned just past the external sphincter muscles at the entry point of the anal canal thereby enabling the sphincter muscles to be stimulated if need be and gastrointestinal gases and faeces to be discharged. With this in mind, the length of the forward portion 8 of the shaft 5 should be at least 30 mm for adults and in the range of about 15-35 mm for infants.

Once the device 1 is located in the operative position, the annulus 7 between the elongate shaft 5 and wall of the lumen 4 of the tube element 3 acts to channel into the lumen 4 of the tube element 3 faeces not discharged into the lumen 4 via the channel 9 in the elongate shaft 5. A bag (not shown) secured to the tube element 3 as in WO99/30652 *supra* collects the faeces and gases discharged into the lumen 4 through the channel 9 and annulus 7. Alternately, the tube element 3 could have a sealed rear end so that the tube element 3 acts as a container for the faeces and gases.

It will be understood that the invention has been illustrated by an exemplary embodiment and that the invention can be varied in many ways within the ambit of the appended claims. For instance, the rectal insertion device can be made from many other plastic materials besides Pebax™. It will further be understood that the inclusion in the claims of reference numerals from the Figures of drawings is for illustration and not to be construed as having a limiting effect on the claims.

**CLAIMS**

1. A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient having a body (3, 5) comprising a forward section (8) which in an operative position of the device is disposed in the anal canal of the patient and a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section characterised in that the device further comprises a rearward section (3) having a forward end which in the operative position is disposed extra-corporeally and a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section.  
5
2. A rectal insertion device as claimed in claim 1, characterised in that in the operative position of the device the forward end of the rearward section abuts  
10 with the anus of the patient.  
15
3. A rectal insertion device as claimed in claim 1 or 2, characterised in that the forward end of the rearward section has a transverse dimension greater than the transverse dimension of the forward section and that the forward section  
20 extends forwardly from the forward end of the rearward section.
4. A rectal insertion device as claimed in claim 1, 2 or 3, characterised in that the forward section and rearward sections are co-axially arranged.  
25
5. A rectal insertion device as claimed in claim 3 or 4, characterised in that the second forward opening is an annulus (7) formed around the forward section.  
30
6. A rectal insertion device as claimed in any one of claims 1 to 5, characterised in that the first passageway communicates with the second passageway.

7. A rectal insertion device as claimed in any one of claims 1 to 6, characterised in that the second passageway has a rearward opening in the rearward section.
8. A rectal insertion device as claimed in claim 7, characterised in that the rearward section of the device is a tube element (3) having an open-ended axial lumen.
- 10 9. A rectal insertion device as claimed in claim 8, characterised in that the device comprises an elongate shaft (5) having a forward portion (8) which presents the forward section of the device and a rearward portion which extends rearwardly from the forward portion into the lumen of the tube element and through which the first passageway extends.
- 15 10. A rectal insertion device as claimed in claim 9, characterised in that the first passageway has a rearward opening (13) in the rearward portion of the elongate shaft.
- 20 11. A rectal insertion device as claimed in claim 9 or claim 10, characterised in that the rearward portion of the elongate shaft is spaced from, and attached to, the wall of the lumen through one or more ribs (6).
- 25 12. A rectal insertion device substantially as herein described with reference to, and as illustrated by, the accompanying Figures of drawings.

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ABSTRACTRectal Insertion Device

- 5 A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient having a body (3, 5) comprises a forward section (8) which in an operative position of the device is disposed in the anal canal of the patient, a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section, a rearward section (3) having a  
10 forward end which in the operative position is disposed extra-corporeally and a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section. The second passageway acts to catch faeces discharged from the anal canal not caught in the first passageway.

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(Fig. 1)

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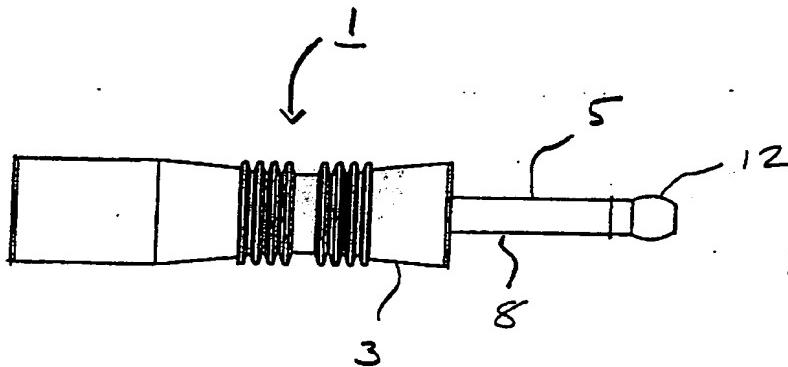


FIG. 1

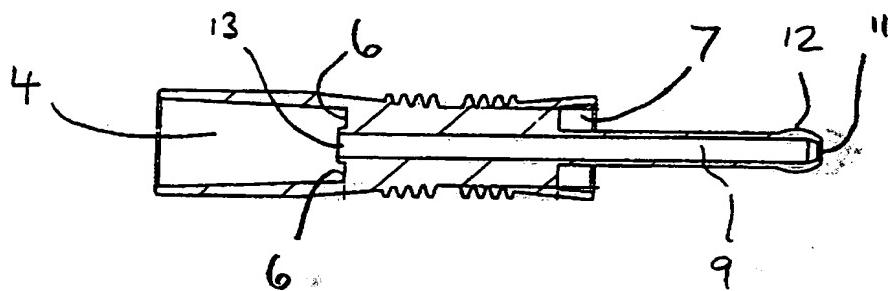


FIG. 2

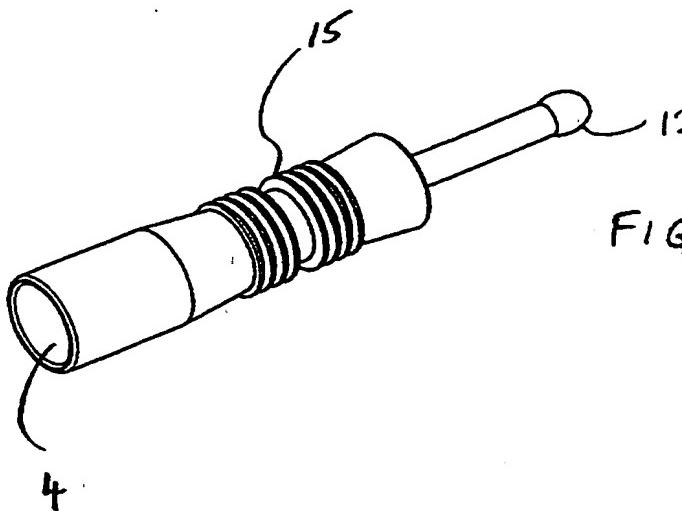


FIG. 3

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